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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/738,066	12/15/2000	John M. Nuss	1647.002	1181

7590

10/21/2002

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 10/21/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/738,066

Applicant(s)

NUSS ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8-19-02 (RCE).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 6-35, and 40-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-9, 11-35, 40-43, and 45-74 is/are rejected.
- 7) ☒ Claim(s) 10 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 8-19-02 has been entered.

Pending claims are 1, 6-35, and 40-74.

Specification

2. The disclosure is objected to because of the following informalities: On page 9, the specification has been amended to include a ring of (R₈, R₉)-Phenyl-Y. However, this variable Y has a definition that is different from the one for variable Y on page 6. Such an inconsistency results in confusion.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

Art Unit: 1624

connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 6-9, 11-35, 40-43, and 45-74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds of formula I (as recited in claims 1 and 35) with A₁ as (R₈, R₉)-Phenyl-NH, does not reasonably provide enablement for those with A₁ as (R₈, R₉)-Phenoxy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In the specification, it appears that when X and Y represent nitrogens (i.e., the side chain of -N-CH₂CH₂-N-), then A₁ is not (R₈, R₉)-Phenoxy. The only two species with A₁ as a substituted phenoxy are described in Examples 8 and 9. Said species do not have the side chain of -N-CH₂-CH₂-N-. With no generic reaction scheme for the combination of a substituted phenoxy and -N-CH₂-CH₂-N-, one skilled in the art will have to carry out undue experimentation for making compounds of formula I having such a combination. Even the closest prior art, Thomae (GB'383), does not provide guidance for said combination. Furthermore, compounds with substituted phenoxy in the side chain [-N-CH₂-CH₂-N-] have never been tested for inhibitory activity on GSK3, nor have they been tested for activity in treating any disorder. Thus, not only one skilled in the art has to develop a process for making said compounds, they will have to develop a bioassay method for establishing any kind of activity for those compounds. Such tasks require undue experimentation since the pharmaceutical art is unpredictable, and the guidance is limited.

Claim 74 is further rejected for not having sufficient guidance in the treatments of Alzheimer's disease, and Syndrome X. Note, compounds 3-19 are tested for activity on GSK3, and glucose tolerance test. Said activities do not bear any correlation to Alzheimer's disease or Syndrome X. On page 16, GSK3 is described as affecting glycogen production. Thus, a direct effect of GSK3 on diabetes is justified. Alzheimer's disease and Syndrome X, however, have never been associated with glycogen production. The state of the art currently treats Alzheimer's disease with a choline esterase inhibitor, or an agent that prevents amyloid formation. Likewise, it is not understood how an increase in glycogen production can help a patient having hyperinsulinemia in Syndrome X. Again, undue experimentation is needed for one skilled in the art to treat said disorders with GSK3 inhibitors since their etiologies do not seem to be tied with GSK3.

Claim Objections

4. Claims 10 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:00-5:30).

Art Unit: 1624


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

October 17, 2002


Mukund Shah
Supervisory Patent Examiner
Art Unit 1624